

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Re Patent Application of:

Orville G. KOLTERMAN *et al.*

Appl. No.: 10/643,681

Filed: August 18, 2003

For: *Methods for Regulating Postprandial
Blood Glucose (As Amended)*

Confirmation No.: 4614

Art Unit: 1639

Examiner: LIU, Sue Xu

Atty. Docket: 18528.642/ 254/057CON

**Response to Notice to Comply with Requirements for Patent Applications
Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures**

Mail Stop Sequence
Commissioner for Patents
P.O. Box 22313-1450
Alexandria, VA 22313-1450

Sir:

This submission is in response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures mailed March 8, 2006 in connection with the above-identified application. The deadline for response to this Notice is April 8, 2006. Accordingly, this response is timely filed.


Applicants submit the following for appropriate action by the U.S. Patent and Trademark Office:

1. Copy of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (4 pages);
2. Response to Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures (3 pages);
3. Substitute Sequence Listing in computer readable form (CRF) on 3.5 inch diskette;
4. Substitute Sequence Listing in paper form (27 pages);
5. Amendment in Response to Notice under 37 C.F.R. §§1.821-1.825 (15 pages); and

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8a

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient First Class postage in an envelope addressed to the Mail Stop Sequence, Commissioner for Patents, P.O. Box 22313-1450, Alexandria, VA 22313-1450, on the date shown below.

April 5, 2006
Date of Deposit


Signature of Person Mailing Paper

Amanda S. Halverson
Name of Person Mailing Paper

6. Return receipt postcard.

The substitute Sequence Listing and the accompanying Amendment in Response to Notice under 37 C.F.R. §§1.821-1.825 are being provided to comply with the requirements of 37 C.F.R. §§1.821-1.825. The substitute Sequence Listing submitted herewith replaces all previously submitted Sequence Listings for the above-referenced application. Support for the inclusion of SEQ ID NO identifiers and the Sequence Listing can be found throughout the specification and claims as originally filed, for example, at pages 16-17, and pages 43-45, 48 and 49 of the substitute specification filed May 10, 2005. No new matter is added by these amendments. Applicants respectfully request entry of the substitute Sequence Listing.

This submission, filed in accordance with 37 C.F.R. §§1.821(g) and 1.825(a), does not include new matter.

A paper copy of the substitute Sequence Listing and a computer readable form (CRF) of the sequence listing on 3.5 inch diskette are herein incorporated by reference. The information contained on the diskette is as follows:

Machine Format: IBM-PC
Operating System Compatibility: MS-Windows
File Name: 254057CON.ST25.txt
File Size: 30 KB
Date Data Recorded on Diskette: April 5, 2006

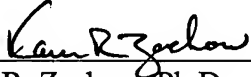
In accordance with 37 C.F.R. §1.821(f), I hereby state that information recorded in computer readable format (CRF) is identical to the written sequence listing filed herewith.

No fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,

AMYLIN PHARMACEUTICALS, INC.

Date: April 5, 2006



Karen R. Zachow, Ph.D.
Registration No. 46,332

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UNITED STATES PATENT AND TRADEMARK OFFICE

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254/057CON

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,681	08/18/2003	Orville G. Koltermann	254/057CON	4614

44638 7590 03/08/2006
ARNOLD & PORTER LLP (18528)
555 TWELFTH ST, NW
WASHINGTON, DC 20004

EXAMINER

LIU, SUE XU

ART UNIT PAPER NUMBER

1639

DATE MAILED: 03/08/2006 ✓

SEQ RSP

Please find below and/or attached an Office communication concerning this application or proceeding.

RSP 4/8/06 /
DD 7/8/06 /

Resp.
Docketed
Due Date 4/8/06
Initial as



A
m3
80



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APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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10/643,681

EXAMINER

SL

ART UNIT	PAPER
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1639

20060304

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

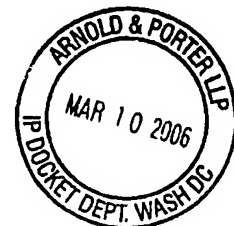
Commissioner for Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR §§ 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (<<<http://www.uspto.gov/efc/efs/downloads/documents.htm>>>), EFS Submission User Manual - ePAVE)
2. Mailed to: Mail Stop Sequence
Commissioner for Patents
P.O. Box 22313-1450
Alexandria, VA 22313-1450
3. Mailed by Federal Express, United Parcel Service or other delivery service to:
U. S. Patent and Trademark Office
Box Sequence, Room 1B03-Mailroom
Crystal Plaza Two
220 20th Street S.
Arlington, Virginia 22202
4. Hand Carried directly to the Customer Window at:
U. S. Patent and Trademark Office



Box Sequence, Customer Window, Lobby, Room 1B03
Crystal Plaza Two
220 20th Street S.
Arlington, Virginia 22202

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sue Liu
3/6/06



Notice to Comply	Application No. 10643681	Applicant(s) KOLTERMAN ET AL.	
	Examiner Sue Liu	Art Unit 1639	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set in the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: The instant Claims (e.g. Claim 25) recite lists of sequences, which are identified by sequence names and are NOT in compliance with Sequence Rule. Reference to sequences in both specification and claims must be accompanied by proper sequence identifier, i.e. SEQ ID Nos. Applicants are requested to amend the instant specification and claims accordingly.

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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